

DATE OUT: _____

SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]
DP BARCODE No.: D226250 REG./File Symbol No.: 524-UOG
PRODUCT NAME: MON 58420 Herbicide

DATE: September 12, 1996

TO: Robert Taylor, PM 25
Fungicide-Herbicide Branch
Registration Division(7505C)

FROM: Shyam B. Mathur, Ph.D., Chemist
Product Chemistry Review Section
Registration Support Branch/RD (7505W)

THRU: Harold Podall, Ph.D., Section Head
Product Chemistry Review Section
Registration Support Branch/RD(7505W)

Signature
9-17-96

2H P
9/18/96

SUMMARY OF FINDINGS

1. The basic formulation CSF(dated April 15, 1996) is filled out correctly and completely in compliance with PR Notice 91-2 and agree with the label claim nominal concentration.[61-1 & 62-2].
2. The data submitted corresponding to guideline reference 61-2 and 61-3 satisfy the data requirements of 40CFR§158.165 and 158.167 respectively.
3. The data submitted corresponding to guideline reference 62-1 and 62-3 satisfy the data requirements of 40CFR§158.170 and 158.180 respectively.
4. The data submitted corresponding to guideline reference 63-3,7, 12,14-16,18, & 21 satisfy the data requirements of 40CFR §158.190. The registrant informed that the studies on storage stability(63-17) and corrosion characteristics will be initiated this year(1996).
5. The registrant carried out analysis for following nitrosamines: N-nitrosoglyphosate(NNG), N-nitrososarcosine(NNSAR), N-nitroso-methylaminomethyl phosphonic acid(NNMAMPA), N-nitrosoiminodi-acetic acid(NNIDA), and N-nitrosoimino-bis-methylene-bis-phosphonic acid(NNTB). Out of all these nitrosamines, only N-nitroso glyphosate(NNG) was detected in less than 1 ppm.

Note to PM:

- a. The acetochlor [REDACTED] has been shown to be [REDACTED] in REFS, whereas the registrant in CSF indicated it to be [REDACTED]
- b. N-Phosphonomethylglycine, MON 0139 isopropylamine salt [REDACTED] has been shown to be [REDACTED] in REFS, whereas the registrant in the CSF indicated it to be [REDACTED]

7505W:RD:RSB:PCRS:CS-

1:Rmxxx:Reviewer:S.B.MATHUR:09/12/96:703-308-8378:Code No.(Reg. No 524-UOG). <PCFORM>

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

PRODUCT CHEMISTRY REVIEW OF MP ☐ EP ☒
 DP BARCODE No.: D226250 REG./File Symbol No.: 524-UOG
 PRODUCT NAME: MON 58420 Herbicide
 DATE: September 12, 1996

1. Reviewer: S.B.Mathur 2. Company: Monsanto Agriculture Co.
3. Type of Submission: Registration ☒ Reregistration ☐
 New ☒ Resubmission ☐ Amendment ☐ "ME-TOO" ☐
 Alternate Formulation ☐ Experimental Use Permit ☐
 Other (Specify) _____
4. If "Me-TOO" Registration, this product is ☐ is not ☐
 similar or substantially similar to EPA's Reg. No.: _____

If not, comment in Confidential Appendix A on the differences between the registered and the new source where significant.

CONFIDENTIAL STATEMENT OF FORMULA

5. Type of formulation and the sources of active ingredients:
- Non-integrated formulation system.....☒
 - Are all technical grade active ingredients used registered?
 • yes ☐ • no ☐ , If no, specify _____
 - Integrated formulation system.....☐
6. Clearance of intentionally added ingredients in the formulation for the intended use (indicate in the Confidential Appendix those that are not cleared; the PC Codes should be provided by the chemist on the CSF for those that are cleared):
- 6(a) Formulation intended for food use under 40CFR§180.1001:
 • yes ☒ • no ☐ • Some are cleared, others are not ☐
 Cleared under list: • c☒ • d☒ • e☒
 Are there any limitations for use as an inert under 40CFR§180.1001?
 • yes ☐ • no ☐ , If yes, specify _____
- 6(b) Formulation intended for non-food use:
 • yes ☐ • no ☒ • Some are cleared, others are not ☐
- 6(c) Clearance by the FDA of certain formulations under 21CFR§170 to 199. Examples: (a) indirect food additives, such as food contact surface sanitizers; adhesives, coatings, paper and paperboard products that may contact food in packaging or holding; and (b) substances generally recognized as safe (GRAS).
 • yes ☐ • no ☐ • Some are cleared, others are not ☐
 If yes, the entire formulation is cleared under 21CFR§_____.

7. The density, pH, and flammability values given on the CSF are identical with those of GRN 63-7, 63-12, and 63-15, respectively: • yes [X] • no []
8. The nominal concentrations (NC) of the active ingredients and the upper and lower certified limits (UCL & LCL) are as follows:

Active ingredient(s)	% by weight		
	NC	UCL	LCL
Acetochlor [REDACTED]	(21.50)		
MON 0139 Isopropyl amine salt [REDACTED]	(8.10)		
Atrazine [REDACTED]	(16.10)		

9. The calculated NCs, based on the pure active ingredients (PAI), are identical to those on the label: • yes [X] • no []
10. The certified limits are within the standard limits as per 40CFR§158.175 or are adequately explained if different: • yes [X] • no []

PRODUCT LABEL

11. The chemical names of the active ingredients on the label are identical to those on the CSF: • yes [X] • no []
12. The appropriate physical and chemical hazards statement regarding flammability or explosive characteristics of the product are given on the label: • yes [] • no [] • not applicable [X]
13. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses: • yes [X] • no []

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

PRODUCT CHEMISTRY DATA (SERIES 61, 62, 63)

14. <u>Chemical IDs/Manufacture/ Analytical Information</u>	<u>Data Required Fulfilled</u>	<u>MRID No.</u>
61-1 Chemical Identity(CSF)	Y	04-15-96
61-2 Start.Mat.& Mfg.Process	Y	440004-01
61-3 Discussion of Impurities	Y	" "
62-1 Preliminary Analysis	Y	" "
62-2 Certified Limits(CSF)	Y	04-15-96
62-3 Enforcement Analytical Method	Y	440004-01

15. <u>Physical/Chemical</u>	<u>Pro per tie s</u>	<u>Data Required Fulfille d</u>	<u>Value or Qualitat. Descrip.</u>	<u>MRID No.</u>
63-3 Physical State		Y	Liquid	" "
63-7 Density/Bulk Density		Y	9.3 lbs per gal.	" "
63-12 pH of Product		Y	5.48	" "
63-14 Oxid/Red Action		Y	Note 1	" "
63-15a Flamma.-Flsh.Pt.		Y	>210°F	" "
63-15b Flame Extension		NA		
63-16 Explodability		Y	None	" "
63-17 Storage Stability		I	Note 2	" "
63-18 Viscosity		Y	682 cPs at 30 RPM	" "
63-19 Miscibility		NA		
63-20 Corros.Charact.		I	Note 2	" "
63-21 Dielec.Bkd.Vltg.		NA		

Explanations: Y = The Requirements Were Fulfilled; N = The Requirements Were Not Fulfilled; NA = Not Applicable; G = Data Gap; U = Requires Upgrading; I = Incomplete or In Progress; W = Waived.

Note 1. 63-14. Oxi./Red. Property: The reagents were added to the EP in a mass ratio 5:1 of EP to the reagent. The reagents used were water, Zn, $\text{NH}_4\text{H}_2\text{PO}_4$, and 1% KMnO_4 . The product was oxidized by 1% KMnO_4 .

Note 2. 63-17 and 63-20.: the registrant reported that these two studies will be initiated together in 1996.

Product Chemistry Review for 524-493 dated 9/18/96

Page _____ is not included in this copy.

Pages 5 through 8 are not included.

The material not included contains the following type of information:

- ____ Identity of product inert ingredients.
- ____ Identity of product impurities.
- ____ Description of the product manufacturing process.
- ____ Description of quality control procedures.
- ____ Identity of the source of product ingredients.
- ____ Sales or other commercial/financial information.
- ____ A draft product label.
- ☒ The product confidential statement of formula.
- ____ Information about a pending registration action.
- ____ FIFRA registration data.
- ____ The document is a duplicate of page(s) _____.
- ____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater.

This chemical demonstrates the properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the ground water is shallow, may result in ground water contamination.

Acetochlor has properties that may result in surface water contamination via dissolved runoff and erosion. Practices should be followed to minimize the potential for dissolved runoff and/or runoff erosion.

Physical or Chemical Hazards

Spray solution of this product should be mixed, stored and applied only in stainless steel, aluminum, fiberglass, plastic and plastic-lined steel containers.

DO NOT MIX, STORE OR APPLY THIS THIS PRODUCT OR SPRAY SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS. This product or spray solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury, if ignited by open flames, sparks, welder's torch, lighted cigarette or other ignition sources.

ACTIVE INGREDIENTS:*

Acetochlor, [2-chloro-N-ethoxymethyl-N-(2-ethyl-6-methylphenyl)acetamide]	21.5%
Atrazine, [2-chloro-4-(ethylamino)-6-(isopropylamino)s-triazine] and related triazines	16.1%
Glyphosate, [N-phosphonomethyl]glycine, in the form of its isopropylamine salt	8.1%
INERT INGREDIENTS:	54.3%

	100.0%

*Contains 240 grams/liter or 2.0 pounds/gallon of acetochlor, 180 grams/liter or 1.5 pounds/gallon of atrazine and related compounds and 90 grams/liter or 0.75 pound/gallon of glyphosate, in the form of its isopropylamine salt which is equivalent to 0.56 pounds/gallon of the acid, glyphosate.

This product is protected by U.S. Pat. No. 4,256,481 and U.S. Patent No. 4,405,531. Other patents pending. No license is granted under any non-U.S. patent(s)